

## § 405.205

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

### **§ 405.205 Coverage of a non-experimental/investigational (Category B) device.**

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

### **§ 405.207 Services related to a non-covered device.**

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in § 405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination proc-

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ess; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in § 405.201(b) that is furnished in conjunction with an FDA-approved clinical trial.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004]

### **§ 405.209 Payment for a non-experimental/investigational (Category B) device.**

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

### **§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.**

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

### **§ 405.213 Re-evaluation of a device categorization.**

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

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(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

### § 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

### Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u,

1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

#### GENERAL PROVISIONS

### § 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

#### LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

### § 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the third year following the year in